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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,142	07/24/2003	Paul A. Burgio	58359US003	9324

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EXAMINER

GRAFFEO, MICHELLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,142

Applicant(s)

BURGIO ET AL.

Examiner

Michelle Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-80 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/8/05; 8/17/04; 7/28/04</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Action

Claims 1-80 are pending and examined

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8-11, 14-19, 22, 30-34, 36-48, 50-80 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,312,668 to Mitra et al.

Mitra et al. teach coatings on hard tissue surfaces of the oral environment (see col 1 line 9) having a repeat unit derived from an ethylenically unsaturated monomer containing at least one polar or polarizable group (see col 3 lines 42-45) and a method for application (see claim 1 (a) in col 47) wherein the coating can be in an aqueous form or in solution (see col 15 lines 63). The coating described in Mitra et al. comprises:

- A whitening agent such as hydroperoxide and optionally hydrogen peroxide (see col 17 lines 52-58) present in an amount of from about 0.01 to about 10% (see col 17 lines 61-64) wherein about 10% is interpreted to include an amount over 10%,
- A polymer made up of monomer repeat units comprising acrylic acid and itaconic acid for example (see col 4 lines 7-10),

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- A repeating unit comprising a graft polysiloxane (see col 2 line 16),
- A fluoride counterion (see col 4 line 58) and fluoroacrylates (see col 5 line 61),
- A modulating group (see col 2 line 15), and
- A functional group such as a crosslinkable group (see col 10 lines 26-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-7, 12-13, 20-21, 23-29, 49 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,312,668 to Mitra et al. as applied above taken with EP 0363095 to Minnesota Manufacturing and Mining Company.

Mitra et al. do not recite tetrafluoroborate ions such as trimethylammoniummethyl methacrylate tetrafluoroborate as a fluoride releasing group.

The EP 0363095 reference discloses tetrafluoroborate ions as fluoride releasing groups. EP 0363095 does not recite trimethylammoniummethyl methacrylate tetrafluoroborate as a specific fluoride releasing group, but one skilled in the art would find it obvious in light of the non-exclusive list of tetrafluoroborate groups on page 4 lines 21-25 of The EP 0363095 reference.

One skilled in the art would be motivated to combine Mitra et al. with the EP 0363095 reference and as combined would make obvious above claims. Both references are directed to polymeric dental compositions which provide fluoride to the oral cavity. As stated in EP 0363095 on page 2 beginning on line 13, fluoride use in the dental industry is well known. Therefore, one skilled in the art looking to include a fluoride releasing component to a dental care composition would expect success by substituting one fluoride component for another that has been taught as effective in a like composition and wherein the like composition is directed to the same use. Thus, the claimed invention of the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 8-11, 37-40, 47, 51, 57-60 and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,312,668 to Mitra et al. as applied above taken with US Patent No. 6,312,666 to Oxman et al.

Mitra et al. teach a whitening agent such as a peroxide present in an amount from about 0.5 to about 10% of the composition.

Oxman et al. further teach that oxides such as carbamide peroxide can be present in an amount of from 3 to about 40% (see col 6 lines 2-5).

One of skill in the art would be motivated to combine Mitra et al. with Oxman et al. and as combined would make obvious the above claims. Both Mitra et al. and Oxman et al. are directed to oral care compositions and teach the use of a whitening agent. The amount of a whitening agent employed is normally a matter of preference subject to routine optimization of one of ordinary skill in the art. Thus, the amount may be varied in order to obtain the result desired in the final product. Such variations are within the capabilities of those skilled in the art without the need for undue experimentation. Thus, the claimed invention of the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,312,668 to Mitra et al. as applied above taken with US Patent No. 4,018,732 to Lakshmanan.

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Mitra et al. do not recite the hydrophobic hydrocarbon octadecylacrylate specifically.

Lakshamanan discloses an oral adhesive material with includes octadecyl acrylate (see col 1 lines 54-55).

One of skill in the art would be motivated to combine Mitra et al. with Lakshamanan and as combined would make the above claim obvious. Both references are directed to oral care compositions. Further, Mitra et al. describe a hydrophobic composition (see col 2 line 16) such that one skilled in the art would expect success by substituting the octadecyl acrylate of Lakshamanan for the graft polysilixane of Mitra et al. Thus, the claimed invention of the composition was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

No claim is allowed.

US Patent Nos. 5,607,663, 5,866,630, 5,876,208 and 5,888,491 are considered equivalents to 6,312,668 to Mitra et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15 July 2005

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